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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/121,300	07/23/1998	BRUCE G. KANIA	3295-0024-0C	3160

8698 7590 03/08/2006  
STANDLEY LAW GROUP LLP  
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EXAMINER

WILLSE, DAVID H

ART UNIT PAPER NUMBER

3738

DATE MAILED: 03/08/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

Application No.

09/121,300

Applicant(s)

KANIA ET AL.

Examiner

Dave Willse

Art Unit

3738

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 15 December 2005.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) See Continuation Sheet is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) See Continuation Sheet is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
Paper No(s)/Mail Date 1-9-05
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_

Continuation of Disposition of Claims: Claims pending in the application are 75-78,80,85,88,89,92-94,96,99,102,103,106,107,110,111,114,115,118-121 and 124-165.

Continuation of Disposition of Claims: Claims rejected are 75-78,80,85,88,89,92-94,96,99,102,103,106,107,110,111,114,115,118-121 and 124-165.

In the Information Disclosure Statement of January 9, 2006, some of the “related cases” were not considered because a complete copy (37 C.F.R. § 1.98(a)(2)) was not presented.

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 110, 111, and 141-149 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claims contain subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventors, at the time the application was filed, had possession of the claimed invention. The cushioning gel being “nonporous” (claim 110, line 4) is not supported by the original disclosure, as previously explained in the Office action of August 11, 2005.

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 75, 78, 80, 85, 106, 107, 114, 115, 134, 135, 138, 152, 153, and 156 are rejected under 35 U.S.C. 102(b) as being clearly anticipated by Silipos Silosheath #12155. (According to the Information Disclosure Statement of June 4, 2004, Silosheath #12155 corresponds to item no.

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1215 on the Silipos invoice dated November 1, 1993.) The model submitted is clearly of a fabric coated seamlessly on only an inside surface with a polymeric cushioning material, and the accompanying brochure states that said material is a patented gel formulated with medical grade mineral oil. Given an appropriately sized and shaped amputation stump, the gel substantially (MPEP § 2173.05(b)) conforms to the shape of said stump when the liner is worn.

Claims 88, 89, 126, 127, 136, 137, 139, 140, 154, 155, 157, and 158 are rejected under 35 U.S.C. 103(a) as being unpatentable over Silipos Silosheath #12155. Regarding claims 88, 89, and others, biocides and vitamins were well known in the art at the time of the present invention and would have been obvious in order to prevent infection and promote healing. Regarding claim 126 and others, docking means molded to liners were likewise common in the art and would have been obvious in order to affix the Silosheath to the stump socket.

Claims 76, 77, 80, 92-94, 96, 99, 102, 103, 107, 110, 111, 115, 118-121, 124, 125, 128-133, 141-151, and 159-165 rejected under 35 U.S.C. 103(a) as being unpatentable over Silipos Silosheath #12155, in view of Mushenko et al., SU 1739990 A1. Regarding claim 76 and others, cushioning material thickened at distal portions and thinner at posterior upper and middle portions is taught by Mushenko et al. (English translation of Mushenko et al.: page 5, lines 14-16; page 6, lines 5-9) and would have been obvious for the Silipos Silosheath in order to customize the fit for a particular amputee and to reduce trauma to skin at local bony prominences (*ibidem*: page 3, line 1), with further motivation being provided by both references being directed to “improving the performance of cushions” (*ibidem*: page 3, lines 1-2).

The Applicant's remarks have been considered but are deemed to be moot in view of the new grounds of rejection presented above.

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Dave Willse whose telephone number is 571-272-4762. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Corrine McDermott, can be reached on 571-272-4754. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

A handwritten signature in black ink, appearing to read 'Dave Willse', with a stylized, flowing script.

**Dave Willse**  
**Primary Examiner**  
**Art Unit 3738**